# Product Mix Analysis in Manufacturing Line

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## Abstract

This research project was focused on the Product Mix Analysis of a Medical Device manufacturing line due to a customer complaint. Product mix is manufacturing defect and is defined as a mix of components/ assembly product in a batch or mix of different batches of the same component/ assembly product.

DMAIC methodology was used in order to find a root cause and implement a corrective action in the product mix defect. DMAIC is a five-step method for improving existing process problems with unknown causes[1]. The phases or stages of DMAIC include Define, Measure, Analyze, Improve and Control.

In this case eliminating the product mix defect in the manufacturing line, will increase the yield, eliminate customers complaints for product mix defect and reduce rework.

This research seeks to eliminate product mix defect. The importance to eliminate this defect will reduce rework, customer complaints, increase the customer satisfaction and maintain product compliance.

## Introduction

Medical device manufacturers contribute to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health, and extend life.

Focusing on the Quality to comply with requirements and customers satisfaction, there are a lot of challenges in the manufacturing line. One of the challenges are the customer complaints received about Reservoir product. The Reservoirs are a disposable single use medication container intended for use with the external infusion pump. The reservoir system consists of a hollow barrel and movable stopper. A removable plunger rod is attached to the stopper in order to fill the reservoir. The reservoir is placed in an external infusion pump and attaches to an infusion set by means of a proprietary tubing connector instead of a standard Lure connector.

Customer complaints are the customer's way of expressing their dissatisfaction towards your product, service, or any other business aspect.

This research project will be focused on eliminating and implement preventive and corrective actions of the product mix defect on the Reservoirs manufacturing line to reduce or eliminate customer complaints.

## Background

During a complaint verification of a product mix of reservoir product, additional evaluation was requested since reported complaint could potentially be originated at the manufacturing process. Customer reported receiving a box of X size of reservoir product with one of ten Y size of reservoir product in the box. The customer was unable to fit the reservoir inside the X size pump's compartment.

## Problem

Product mix defect is increasing in reservoir manufacturing line. Customer complaint was received, the size of a reservoir does not match the size specified in the customer box. There are 2 sizes (X and Y) of reservoirs product on the manufacturing line. The manufacturing process of the reservoir product requires a constant change over of these 2 sizes due to the receiving demand. With a decrease or elimination of product mix defect, customers complaints for this defect will reduce or eliminate. In the next investigation, will be implemented the DMAIC methodology to achieve the goal of eliminate product mix defect to avoid customer complaints.

## Methodology

The DMAIC Problem Solving Approach is a process improvement methodology based on the Six Sigma approach that helps to improve business processes and products. It is used to identify, analyze, and solve existing processes that are inefficient or ineffective. The approach breaks down into five phases: Define, Measure, Analyze, Improve and Control (See Figure 1). Each phase builds upon the previous one to identify potential solutions for the problem at hand. With this method, organizations can focus on eliminating waste and defects while improving customer satisfaction and profitability.


**Figure 1**

**DMAIC Methodology**

### Define

The purpose of the Define phase is ultimately to describe the problems that need to be solved and for the key business decision-makers to be aligned on the goal of the project[4]. At the beginning, you might not even have identified what problem to work on. You'll often use DMAIC tools like Pareto analysis and Supplier-Input-Process-Output-Customer (SIPOC) diagrams to help understand which problems are leading.

### Measure

The Measure phase is about creating and developing a data collection plan for the process. Feedback from people who make products, feedback from customers who use the products, and how the product is processed are ways to collect data to determine how defects are created. The team also looks at business growth strategies. In this phase, the problem statement and project contract are frequently refined as a result of establishing an accurate baseline for the metrics being targeted. This is also known as the data collection step. All relevant data, important for the product, and the processes followed to manufacture the product are collected at this step.

### Analyze

It is the analysis of the data collected in the previous phase. It is important to analyze the feedback given by customers, as they are the end users of the product and for what the product needs to meet their needs. At this stage, the root cause of the problem is identified. A process chart, here, helps the team understand where the product's manufacturing process has gone wrong. Gaps between present performance and desired performance are discovered in this phase, along with sources of variation and possibilities for improvement.

### Improve

During the analyze phase, your understanding of the process will have solidified so that you know what changes to make to improve the process. During the improvement phase, you'll make sure to deliver those improvements to the full process. Innovative solutions are developed during the Improve phase in order to establish and implement the strategy.

### Control

The Control phase seeks maintain and sustain what was implemented. It's critical that make the improvements part of the standard operating procedure for the process. A control plan will be developed that describes the new process, and the implementation of a monitoring plan that lets you verify that the improvements are stable.

## Results and Discussion

### Define

In order to determine the problem statement, the goal of the project, benefits and the metrics that will be defined, Project Charter tool was performed as part of the Define phase. See Table 1.

**Table 1**

**Project Charter**

| Project Charter |
|---|
| **Project Name:** Product Mix Analysis in Manufacturing Line |
| **Process Impacted:** Reservoir's Assembly Process |
| **Problem Statement**: Various complaints were received for product mix defects for reservoir assembly product. These complaints cause a negative impact in the customer satisfaction. Also, product mix defect increases the cost of manufacturing due to rework, investigation and scrap of the product. |
| **Goal:** Mitigate and eliminate the product mix defect in the reservoir manufacturing line. |
| **Benefits:** Eliminate future customer complaints, reduce rework, scrap and labor cost. |
| **Metric Definition:** Product Mix Defect |

### Measure

In order to determine customers' needs and inputs and outputs of the process, Voice of Customers tool and SIPOC tool was performed as part of the Measure phase.

Nonconformities of the process are documented in the Device History Record (DHR) of the batch. All nonconformities were validated, and manufacturing personnel were trained in the process that are executing.

In Table 2 and Figure 2 below, Voice of Customers and SIPOC results are showed.

**Table 2**

**VOC**

| Voice of Customer | Customer issues | Customer Requirement |
|---|---|---|
| What are the customers saying? | What do the customers need? | What is required to fulfill the customers need? |
| The Reservoir is a different size than my insulin pump | Customers need a reservoir of the same size of the insulin pump | - Training<br>- Clarify instructions on procedures<br>- Reduce the quantity of changeovers<br>- Improve quality controls |
| The reservoirs are from different size than packaging batch identification. | Customers need that the reservoirs come from the same batch | |
| Reservoirs are from two different batch numbers. | | |

The voice of customer shows us what are the needs of the customers. The concerns or complaints about the product is that in some cases they are not receiving the product as requested or described in the packaging box. There are various opportunities if the manufacturing process that could help with the customers' requirements. These improvements will be very beneficial not only for the projects but also to increase the satisfaction of the customer.

| Suppliers | Inputs | Processes | Outputs | Customers |
|---|---|---|---|---|
| Who supplies the process inputs? | What inputs are required? | What are the major steps in the process? | What are the process outputs? | Who receives the outputs? |
| Vendors (raw materials suppliers) | Raw materials | Subassemblies process | Reservoir model X<br>Reservoir model Y | Customers (patients) |
| | | Main assembly process | | Medics |
| | | Packaging process | | Pharmacies |

**Figure 2**

**SIPOC**

From the SIPOC analysis it can be determined that the customers want the specific reservoir model from the manufacturing. Also, avoid any nonconformity. The customer wants to receive the product without defects.

Complying with customers' requirements and needs, will be achieve a better customer satisfaction and maintain the customers with the company.

### Analyze Phase

A report of defects was executed with the intention of obtaining an indicator of which process step of the reservoir manufacturing process is causing the product mix defects during the assembly (See Figure 3). This reports along with the customer complaints, will help to identify those requirements that are causing problem and will help to identified which sub-process needs to be worked in order to achieve the goal of zero (0) product mix defect or complaints for reservoir assembly process.

| LOTID | LOT_ORIGINATIONSTE | LOT_DISPO | PRODU | PRB_ST | PRB_REJECT_CODE | PRB_COMMEN | AGING | PRRNUI | QTY |
|---|---|---|---|---|---|---|---|---|---|
| HG3XXQDH56 | MMR_Inspection2_RAM | Accept after C | 7005317(C | Closed | MMR:TransferGuardTight | Transfer guard ap | 7 | 1 | 1800( |
| HG3XXQDH58 | MMR_Inspection1_RAM | Accept after C | 7005317(C | Closed | MMR:TransferGuardTight | Transfer guard ap | 7 | 1 | 1200( |
| HG3YAH1H10 | MMR_Inspection1_PAD | Accept after C | 7005290(C | Closed | MMR:FailVolumetricTest | Volumetrica alta. | 9 | 1 | 600( |
| HG3YAH1H11 | MMR_Inspection1_PAD | Accept after C | 7005290(C | Closed | MMR:FailVolumetricTest | Volumetrica alta. | 9 | 1 | 600( |
| HG3YAH1H12 | MMR_Curing_PAD | Accept after C | 7005290(C | Closed | MMR:FailVolumetricTest | Volumetrica alta. | 9 | 1 | 600( |
| HG3YAH1H13 | MMR_Curing_PAD | Accept after C | 7005290(C | Closed | MMR:FailVolumetricTest | Volumetrica alta. | 9 | 1 | 600( |
| HG3YAH1H14 | MMR_Inspection1_PAD | Accept after C | 7005290(C | Closed | MMR:FailVolumetricTest | Volumetrica alta. | 9 | 1 | 600( |
| HG3YAH1H16 | MMR_Inspection1_PAD | Accept after C | 7005290(C | Closed | MMR:FailVolumetricTest | Volumetrica alta. | 9 | 1 | 470( |
| HG3YB57H03 | InvMMRFFS1Machine | Accept after C | 7005316(C | Closed | MMR:ProductMix | UNKNOWN | 2 | 1 | 1224( |
| HG3YD7AH06 | MMR_Inspection1_FFS | UNKNOWN | 7005566(I | Open | MMR:BentNeedle | Se encontro aguja | 11 | 1 | 1728 |
| HG3YAH1H32 | MMR_Inspection1_PAD | UNKNOWN | 7005290(C | Open | MMR:Miscellaneous | Dent dentro del b | 11 | 1 | 600( |
| HG3YAH1H33 | MMR_Inspection1_PAD | UNKNOWN | 7005290(C | Open | MMR:Miscellaneous | Dent dentro del b | 11 | 1 | 600( |
| HG3YD0PH03 | MMR_Inspection1_FFS | UNKNOWN | 7005566(I | Open | MMR:BentNeedle | UNKNOWN | 10 | 1 | 1728 |
| HG3YB57H11 | InvMMRFFS | UNKNOWN | 7005316(C | Closed | MMR:ImproperPrint | UNKNOWN | 1 | 1 | 1800( |
| HG3XXQDH52 | MMR_Inspection1_RAM | Accept after C | 7005317(C | Closed | MMR:ExcessiveAdhesive | Ajuntando lote co | 1 | 1 | 1800( |
| HG3YE1H06 | MMR_Inspection1_RAM | Accept after C | 7005316(C | Closed | MMR:ExcessiveAdhesive | Ajuntando lote co | 1 | 1 | 1200( |
| HG3YEX5H03 | MMR_Inspection1_FFS | Accept after C | 7005566(I | Closed | MMR:IncorrectPrint | Fallo prueba shipp | 1 | 1 | 1728 |
| HG3YG63H05 | MMR_Inspection1_FFS | Accept after C | 7005566(I | Closed | MMR:Seal<50% | During G2 test QC | 0 | 1 | 1728 |
| HG3YG63H06 | MMR_Inspection1_FFS | Accept after C | 7005566(I | Closed | MMR:Seal<50% | During G2 test QC | 0 | 1 | 288 |
| HG3YEX5H08 | MMR_Inspection1_FFS | Accept after C | 7005566(I | Closed | MMR:BentNeedle | Transfer Guard wa | 1 | 1 | 1728 |

**Figure 3**

**Reservoirs Defects by process**

It is observed that the product mix defect was originated at the packaging process. Customer complaints were evaluated, and it could be inferred that the cause of the defect was created as found in the report.

In order to reduce defects a 6M Fishbone Analysis (Manpower, Methods, Mother of Nature, Measurements, Materials, Machine) or cause-and-effect diagram was generated to determine the potential contributors to reduce product mix defect (See Figure 4).

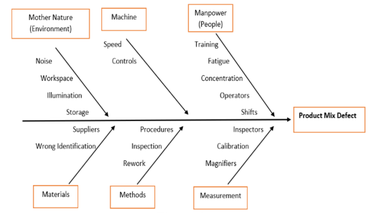


**Figure 4**

**Cause and effect Diagram (Fish Bone Diagram)**

The analysis of the data collected shows that the training, lack of instructions on procedures, machine controls, storage, reworks and inspections are the major contributors.

### Improve Phase

According to the contributors, the following updates and implementation of controls were pursued in the reservoir manufacturing process in order to eliminate or avoid product mix defect.

- Eliminate reclaim process from Bolus and Basal test
- Improve sorting activity for Product Mix defect adding another 100% visual inspection (200% visual inspection).
- Clarify visual inspection of reservoirs inside of blister packs to detect Product Mix.
- Replace stainless steel guard by Lexan (transparent) to facility Line Clearance Procedure on packaging lines. Include instruction to perform inspection of this area.
- Modify Kanban area to separate Model X from Model Y.
- Include visual aid (images) of the areas where Line Clearance (Change Over) is performed.

### Control Phase

The main goal of this phase is to establish and implement effective controls to ensure that the identified causes are effectively implemented. Improvements mentioned above will be controlled as follows:

- Instruction was included as part of the change over process to verify thru Lexan if a reservoir is remaining in the line.
- Visual aid was included in the Kanban area (storage) to separate assembly (side by side) from each other.
- Instruction included to procedure to perform 200% visual inspection and a signature in system is required after inspection.
- Refresh training on affected procedures will be required every 6 months.

## Conclusions

The Reservoir assembly process has been improved using the DMAIC tools. The goals of the project were eliminated product mix defect from reservoir assembly line in order to avoid customer complaints and comply to regulatory requirements. Through the result of Six Sigma with the DMAIC methodology we could notice that our process was not robust and that we needed to implement measures to be effective.

## Future Work

Monitoring customer complaints for product mix defect.

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